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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,126	12/22/2003	Marni L. Allen	MCP-5019	8463
27777	7590	10/26/2007		
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER SAMALA, JAGADISHWAR RAO	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 10/26/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/743,126

Applicant(s)

ALLEN ET AL.

Examiner

Jagadishwar R. Samala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Status of Application**

1. Acknowledgment is made of amendment filed on August 20, 2007. Upon entering the amendment, claims 24-53 are amended. The pending claims are 24-53 and presented for the examination. The claims 1-23 are cancelled.

### **Response to Arguments**

2. Applicant's arguments filed on August 20, 2007 with respect to rejection of claims under U.S.C. 102 (b) and 103 (a) have been fully considered but are moot in view of the new ground(s) of rejection due to the scope changes made into the newly amended claims.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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3. Claims 24-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quada Jr. et al (US 2002/0193609 A1) or Weinstein et al (US 5,695,930) in view of Camden (US 2001/0027205 A1).

Quada discloses a pharmaceutical kit useful for the treatment of cancer or viral infection. And kit comprises one or more containers containing a pharmaceutical composition comprising a therapeutically effective amount of a chemotherapeutic agent. And further, kits include, one or more container with one or more pharmaceutically acceptable carriers, and additional containers. And also discloses instructions such as printed instructions for e.g. either the components to be administered, guidelines for administration, and/or guidelines for mixing the components (see para 0156 and 0157).

Weinstein discloses a kit comprising first container containing a solid human immunodeficiency virus antigens, a second container containing a secondary antibody specific for mammalian salivary antibodies and a third compartment containing standard reagents necessary for the reporter molecule to produce a signal.

Quada and Weinstein meet the claim limitation as described above but fails to include flavoring agents in first and second container of the kit.

Camden discloses a pharmaceutical kit useful, for the treatment of cancer, comprising one or more containers containing a pharmaceutical composition comprising a therapeutically effective amount of chemotherapeutic agent and carrier such as coloring agents, flavoring agents and like. And also kit further

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includes, one or more containers with one or more pharmaceutically acceptable carriers, additional containers (see para 0123 and 0124).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the kit to incorporate a flavoring agent in the kit disclosed by Quada and Weinstein. One motivation is provided by Camden in that the kit comprising a pharmaceutical composition comprising a therapeutically effective amount of chemotherapeutic agent along with carrier such as flavoring agent in one or more containers provides for an improved method of packaging a drug delivery kit. The kit form is particularly advantageous when the separate components are preferably administered in different dosage forms (e.g. oral and parenteral) are administered at different dosage intervals. One skilled in the art would recognize that the enhanced properties of kits provide a convenient mechanism to disperse products to consumers. By combining the teachings of Camden with Quada and Weinstein and producing kit comprising a therapeutically effective amount of chemotherapeutic agent and carrier such as coloring agents, flavoring agents and like would provide a convenient mechanism to disperse chemotherapeutic agent to consumers. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to package a chemotherapeutic composition, such as the one advanced in the instant application, in a kit.

***Conclusion***

1. No claims are allowed at this time.
2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE MONTH shortened statutory period, then the, shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jagadishwar R Samala  
Examiner  
Art Unit 1618

Zohreh Fay  
Primary Examiner  
Art Unit 1618

A handwritten signature in black ink, appearing to read 'Zohreh Fay', with a stylized flourish at the end.